

29. (Amended) The composition of claim 23, wherein
- (a) the histamine receptor antagonist is selected from the group consisting of: cetirizine hydrochloride and fexofenadine;
  - (b) the leukotriene receptor antagonist is selected from the group consisting of: montelukast sodium and zafirlukast sodium; and
  - (c) the adrenergic bronchodilator is a beta<sub>2</sub>-adrenergic bronchodilator

**REMARKS**

The present amendment is in response to the Office Action mailed January 3, 2002, in which Claims 14, 15, 23 through 29 and 31 were rejected and Claims 16 through 18, 30 and 32 through 48 were withdrawn from consideration. Applicant has thoroughly reviewed the outstanding Office Action including the Examiner's remarks and the reference cited therein. The following remarks are believed to be fully responsive to the Office Action and, when coupled with the amendments made herein, are believed to render all claims at issue patentably distinguishable over the cited references.

Claims 14, 23, 24, and 29 are amended herein. Claim 31 is cancelled. No claims are added. Accordingly, Claims 14, 15 and 23 through 29 remain pending.

All the changes are made for clarification and are based on the application as originally filed. It is respectfully submitted that no new matter

is added by these changes.

Applicant respectfully requests reconsideration in light of the above amendments and the following remarks.

#### **CLAIM STATUS IN VIEW OF ELECTION**

Applicant acknowledges the final status of the election requirement and the withdrawal from consideration of former Claims 16 through 18, 30 and 32 through 48.

#### **CLAIM OBJECTIONS**

On page 3 of the Office Action the Examiner objected to Claims 23, 24, 29 and 31 because the term "broncodilator" was misspelled. Appropriate correction has been made to Claims 23, 24 and 29 for clarification. Claim 31 has been cancelled.

Applicant respectfully submits that the Examiner's objection is now overcome and should be reconsidered and withdrawn.

#### **CLAIM REJECTIONS – 35 U.S.C. SECTION 103(a)**

On pages 3 and 4 of the Office Action the Examiner rejected Claims 14, 15, 23 through 29, and 31 under 35 U.S.C. Section 103(a) as being unpatentable over WO 97/28797 to Dahlen et al. (hereinafter referred to as "Dahlen et al.") in view of Katzung ("Basic & Clinical Pharmacology," 6<sup>th</sup> ed., 1995, pages 312 through 314 [hereinafter referred to as "Katzung"]).

Applicant respectfully traverses this rejection.

Applicant notes that Dahlen et al discloses an anti-asthma composition comprising (1) loratadine (a histamine receptor antagonist) and (2) montelukast, or zafirlukast, or other compounds (a leukotriene receptor).

Applicant further notes that Katzung discloses a beta<sub>2</sub>-selective drugs for the treatment of asthma, including metaproterenol, albuterol, terbutaline, and bitolterol.

However, Applicant has amended independent Claims 14 and 23 (the only pending independent claims) to define the antihistamine (in Claim 14) and the histamine receptor antagonist (in Claim 23) as being taken from the – group consisting of cetirizine (in Claim 14) or cetirizine hydrochloride (in Claim 23) and fexofenadine-- a combination which is neither taught, suggested, nor is otherwise rendered obvious by the Dahlen et al nor Katzung, whether standing alone or considered in combination.

Applicant thus respectfully submits that the Examiner's rejection under 35 U.S.C. Section 103(a) is now overcome. Reconsideration and withdrawal of this rejection is respectfully requested.

#### **MARKED-UP CHANGES**

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached paper is captioned "**VERSION WITH MARKINGS TO SHOW CHANGES MADE.**"

CONCLUSION

In light of the above amendments and remarks, Applicants respectfully submit that all pending Claims 14, 15 and 23 through 29 as currently presented are in condition for allowance. If, for any reason, the Examiner disagrees, please call the undersigned attorney at 202-624-3947 in an effort to resolve any matter still outstanding *before* issuing another action. The undersigned attorney is confident that any issue which might remain can readily be worked out by telephone.

Favorable reconsideration is respectfully requested.

Respectfully submitted,



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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**  
**(USSN 09/825,258)**

**IN THE CLAIMS:**

Claim 31 is cancelled without prejudice and without dedication or abandonment of the subject matter thereof.

Claims 14, 23, 24 and 29 are amended as follows:

14. (Amended) A composition for the treatment of asthma, the composition comprising:

[montelkast] montelukast sodium;

an antihistamine selected from the group consisting of [cetirizine, loratadine,] cetirizine and fexofenadine; and  
a sympathomimetic bronchodilator.

23. (Amended) A composition for the treatment of asthma, the composition comprising:

(a) a leukotriene receptor antagonist;

(b) a histamine receptor antagonist selected from the group consisting of cetirizine hydrochloride and fexofenadine; and

(c) an adrenergic [broncodilator] bronchodilator.

24. (Amended) The composition of claim 23, wherein the adrenergic

[broncodilator] bronchodilator is a beta<sub>2</sub>-adrenergic [broncodilator]  
bronchodilator.

29. (Amended) The composition of claim 23, wherein

- (a) the histamine receptor antagonist is selected from the group consisting of: cetirizine [hydrochloride, loratadine] hydrochloride and fexofenadine;
- (b) the leukotriene receptor antagonist is selected from the group consisting of: montelukast sodium and zafirlukast sodium; and
- (c) the adrenergic [broncodilator] bronchodilator is a beta<sub>2</sub>-adrenergic [broncodilator] bronchodilator